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**REMARKS**

This is in response to an Office Action mailed on December 14, 2006. The Office Action finally rejected claims 1-3, 5-20, 31 and 32. The application presently includes claims 1-3, 5-20, 31 and 32. No amendments have been made.

The Office Action rejected independent claims 1 and 10 as being anticipated under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,263,680 (Reul Patent). The Office Action alleges that the Reul Patent discloses a medical device (prosthetic heart valve at col. 6, line 29) that comprises a composite (valve member 1, col. 5, line 41) having an inorganic substrate (metal substrate 12, col. 5, ll. 45-47) and a polymer applied on all of the substrate surfaces (blood-compatible synthetic material 14, col. 5, ll. 41-44). The Office Action alleges that the polymer forms a structure shaped differently from the structure of the substrate and provides a form of the device (FIG. 3, hinge flap is formed in one piece with the valve member) and consists of the same blood-compatible synthetic material with which the valve member is coated, integrally cast in the course of the coating process (col. 4, ll. 39-45). The Office Action alleges that the valve ring is coated with the same blood-compatible synthetic material as the valve member at col. 4, ll. 47-49. In the Response to Arguments section, the Office Action makes reference to FIG. 3 of the Reul Patent and alleges that the composite 1 has the shape of a dish which is different from the shape of the inorganic substrate 12.

Applicant again respectfully disagrees that independent claim 1 is anticipated by the Reul Patent. An element of independent claim 1 includes covering an inorganic substrate with a polymer applied on all of the substrate surfaces where the polymer forms a structure that is shaped differently from the structure of the substrate, the polymer providing the form of the device. Applicant maintains the position that a dipping process places a layer having a substantially uniform thickness onto a metal substrate that conforms to the general shape of the substrate. A polymer coating of substantially uniform thickness does not provide a structure that is shaped differently from the structure of the substrate as claimed. Rather, the polymer coating disclosed in the Reul Patent conforms to the shape of the substrate.

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The Office Action makes reference to FIG. 3 which is a cross-section of the valve body taken along section line III-III in FIG. 1. FIG. 3 illustrates a portion of the substrate having an aperture therethrough which, according to the Reul Patent, enables the layers of synthetic material on each side of the metal substrate to be interconnected. In the finished valve member these apertures are completely filled with synthetic material. See col. 5, ll. 48-53.

Referring to FIG. 2 of the Reul patent, the outer surface of the polymer has the same configuration as the outer surface of the metal substrate 12. The apertures 5 are provided in the metal substrate to allow the coating to be interconnected and better retained on the substrate. It is clearly shown that the metal substrate is in the form of a cupped disc and that the polymeric material follows the form of the metal substrate. Therefore, the Reul Patent does not anticipate independent claim 1. Reconsideration and allowance of independent claim 1 are respectfully requested.

The Office Action also alleges that the thickness of the valve members preferably amounts to less than 0.3-0.4 mm. The Office Action alleges that by virtue of its thickness, the composite component is flexible, combined with its composition, which is a metal foil substrate and a flexible synthetic material body, and cites the metal substrate 5, ll. 45-64, and synthetic material at col. 5, ll. 41-44, col. 6, ll. 44-46, and col. 4, ll. 39-45.

Applicant again submits that if the valve flexes, then the response of the valve to the pressure gradient decreases in direct contrast to the disclosure of the Reul patent.

This has the advantage that, compared to traditional valves, very short opening and closing times can be achieved, since the moment of inertia of the thin dish is very small in comparison with spherical or disc valves. This fact guarantees that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber and thus resembles a natural valve more closely than any other existing artificial heart valve. Col. 3, ll. 42-58.

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Further, Applicant does not understand the statement in the Office Action that it is common knowledge that a natural valve is flexible as evidenced by U.S. Pat. No. 4,888,009 and U.S. Pat. No. 5,500,016. The cited passage at col. 3, ll. 42-58 relates to the performance of the valve disclosed in the Reul patent in comparison to other heart valves and a natural heart valve.

There is no disclosure that the heart valve disclosed in the Reul patent flexes as it has a substantially different structure than a natural heart valve and opens and closes in a substantially different manner than a natural heart valve.

A natural heart valve has a distinctly different structure than the heart valve in the Reul Patent. Referring to page 591 of Dorland's Illustrated Medical Dictionary, 23rd Edition, the heart valve has leaflets having edges that move away and contact each other to allow blood to flow through and not backflow. A copy of p. 591 of Dorland's Illustrated Medical Dictionary, 23rd Edition, is attached hereto as Exhibit A. Each of the leaflets in a natural heart valve must flex in order to open and close the valve.

However, the valve in the Reul Patent does not have the structure of a natural heart valve. Rather, the valve of the Reul patent has a cup-shaped disc configuration that is hingedly attached to a vessel wall at one end. The flexing of this cup-shaped valve would reduce the response time of the valve and hinder its performance.

Further, Applicants do not understand the Office Action's inherency argument especially in light of the fact that a flexing member would consume energy that would normally be used to move the cupped valve about its hinge, which is in direct contradiction to the disclosure of the Reul patent. To allege inherency, the Examiner must meet the burden of proof that what is asserted must necessarily happen. *See* MPEP § 2112.

The inherent teaching of a prior art reference is a question of fact that arises both in the context of anticipation and obviousness. *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary

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skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The Examiner has provided no evidence that the cup-shaped valve as disclosed in the Reul Patent must inherently flex. Rather, in contrast, the Reul Patent discloses that it would be disadvantageous for the valve to have flexing capabilities. Therefore, the Examiner has not met the burden in alleging inherency.

For the foregoing reasons, the Reul Patent does not disclose a flexible composite component of a medical device that can be bent through a cross-section of the flexible component. Therefore, the Reul Patent does not anticipate independent claim 10. Reconsideration and allowance of independent claim 10 are respectfully requested.

The Office Action also rejected claims 2, 3, 8, 9, 11, and 16-19 as being anticipated by the Reul Patent. The Office Action also rejected claims 5-7, 12-14, and 31-32 as being obvious over the Reul Patent in view of the Peitsch Patent. The Office Action also rejected claim 15 as being obvious over the Reul Patent in view of the Lenkei Patent. The Office Action also rejected claim 20 as being obvious over the Reul Patent in view of Sumitomo Electric Co. Abstract. While Applicants do not acquiesce to any of the claim rejections, the rejections are moot in light of the fact that independent claims 1 and 10 are in allowable form. Since independent claims 1 and 10 are in allowable form, it follows that dependent claims 2, 3, 5-9, 11-20, and 31 and 32 are in allowable form. Reconsideration and allowance of claims 2, 3, 5-9, 11-20, and 31 and 32 are respectfully requested.

In view of the reasons provided above, it is believed that the pending claims are in condition for allowance. Applicant respectfully requests favorable consideration and early allowance of all pending claims.

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If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Hallie A. Finucane at 612-334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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HAF:PJI:tlr

heat

Plate XVII

591

heart

09/475,724  
14 Feb. 2007

Exhibit A

art from excessive beer drinking. uricular heart block. wander- mally movable heart. wooden- which is enlarged to the left with as seen in the roentgen ray film. t' blok). The condition in which connection between the auricle ariculoventricular band or band pted, so that the auricle and ven- dently of each other (Gaskell), marked by permanent or parox- ia, epileptiform, vertiginous, or , and pulsations of the cervical n rate those of the arteries. The n as Adams-Stokes disease. ar- a form in which there is inter- fine terminal subendocardial kinje system. The electrocardio- hasic curve absent and a nega- a splintered R wave present. ar h., auriculoventricular in the blocking is at the auriculo- ion. bundle-branch h., in- complete h., a condition in al relation between the parts His is destroyed by a lesion, so und ventricles act independently dterventricular h., a form in cle contracts without the other struction in one of the branches His; called also bundle-branch icular h., a form in which the i between the auricles and the at veins and coronary sinus. urn). A burning sensation in the s.

rt'fal-yet). 1. Sudden fatal cast's action. 2. The clinical com inability of the myocardium o maintain an adequate flow of sues of the body. backward by passive engorgement of the sed by a backward rise in pres- heart. congestive h., prot of the ability of the heart to ate flow of blood to the tissues, ination in the amount of blood ard direction by the heart, re- ate supply of blood to the tis- ricular h., failure of proper ventricle, with dyspnea, orthop- ventricular h., failure of f of the right ventricle, with nt, hepatic enlargement, and in.

rt-om'e-ter). An instrument bined sphygmotonomograph and

wot'er). A fatal disease of cat- ts, marked by fluid accumula- pericardium and pleural cavity. ndria ruminantium, which is e ticks *Amblyomma hebraeum*.

verm). *Dirofilaria immitis*.

Gr. thermē). 1. The sensation temperature. 2. The energy sensation of heat. It exists in lar or atomic vibration (ther- may be transferred by conduc- tance, by convection by a sub- tion as electromagnetic waves. animals. atomic h., the uired to raise an atom from 0 tive h., heat applied to the from a heated object, such as onvective h., heat thrown f the body from some outside therapy, heating of the body om the visible and infra-red rum. conversive h., heat n the tissues by the resistance is passage of high-frequency m. delayed h., recovery

